Date of Approval: October 25, 2012

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-496

AMPROMED P for Poultry
(amprolium)

9.6% Oral Solution

Growing chickens, turkeys, and laying hens

For the treatment of coccidiosis in growing chickens, turkeys, and laying hens

Sponsored by:

Cross Vetpharm Group Ltd.

TABLE OF CONTENTS

I. GENERAL INFORMATION:

A. File Number:	ANADA 200-496
B. Sponsor:	Cross Vetpharm Group Ltd. Broomhill Rd., Tallaght, Dublin 24, Ireland Drug Labeler Code: 061623 U.S. Agent: Linda Duple Bimeda, Inc. 2836 Dolliver Park Avenue Lehigh, IA 50557
C. Proprietary Name:	AMPROMED P for Poultry
D. Established Name:	Amprolium
E. Pharmacological Category:	Anticoccidial
F. Dosage Form:	Oral solution
G. Amount of Active Ingredient:	96 mg/mL (9.6%)
H. How Supplied:	128 oz (1 gal) bottle
I. How Dispensed:	OTC
J. Dosages:	Give amprolium at the 0.012% level (8 fl oz AMPROMED P for Poultry per 50 gallons) as soon as coccidiosis is diagnosed and continue for three to five days. (In severe outbreaks, give amprolium at the 0.024% level). Continue with 0.006% amprolium medicated water for an additional 1 to 2 weeks.
K. Route of Administration:	Oral
L. Species/Class:	Growing chickens, turkeys, and laying hens.

M. Indications:	For the treatment of coccidiosis in growing chickens, turkeys, and laying hens. If no improvement is noted within 3 days, have the diagnosis confirmed and follow the instructions of your veterinarian or poultry pathologist. Losses may result from intercurrent disease or other conditions affecting drug intake which can contribute to the virulence of coccidiosis under field conditions.
N. Reference listed new animal drug:	AMPROL; amprolium; NADA 013-149; Huvepharma AD

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the reference listed new animal drug (RLNAD), which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Cross Vetpharm Group Ltd. was granted a waiver from the requirement to demonstrate *in vivo* bioequivalence for the generic product AMPROMED P (amprolium) for Poultry 9.6% Oral Solution. The generic product is administered as an oral solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The RLNAD was approved for use in growing chickens on June 20, 1962; supplemental approval was granted for turkeys and laying hens on August 12, 1964.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

The following are assigned to this product for chickens and turkeys:

- Tolerances for Residues:
  The tolerances established for the pioneer product apply to the generic product. Tolerances are established under 21 CFR 556.50 as follows for residues of amprolium in chickens and turkeys (edible tissues and eggs):
  1. 1 part per million in uncooked liver and kidney.
  2. 0.5 part per million in uncooked muscle tissue.
  3. In chicken and turkey eggs:
     (i) 8 parts per million in egg yolks.
     (ii) 4 parts per million in whole eggs.

- Withdrawal Times:
  Because a waiver from the requirement to demonstrate *in vivo* bioequivalence was granted, the withdrawal times are those previously assigned to the RLNAD product.

  A withdrawal period of 0 days has been established for amprolium in chickens and turkeys.

- Regulatory Method for Residues:
  The validated regulatory analytical method for detection of residues of amprolium is a fluorimetric test. A description of the regulatory method is filed in the Food Additives Analytical Manual that is on file at the Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to AMPROMED P:

- WARNING: Keep this and all drugs out of reach of children. Not for human use.
- PRECAUTIONS: For oral use in animals only. May cause eye irritation. For irritation, flush with plenty of water; get medical attention.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that AMPROMED P, when used according to the label, is safe and effective.